IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

LINDA P. SMITH, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, Defendant.	)	Case No. 1:21-cv-47-HCN-DBP

DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S MOTIONS FOR SUMMARY JUDGMENT

Linda Smith, a Medicare beneficiary, has filed two separate motions for summary judgment, one for each of her legal theories. In the first, she argues that an earlier decision at a lower level of administrative review precluded the Medicare Appeals Council from reaching the decision challenged here. And in the second, she argues that CMS Ruling 1682-R was procedurally flawed and should be vacated by this Court. Before responding to those arguments, it is important to note what Mrs. Smith is not contending here: that either CMS Ruling 1682-R or the challenged decision of the Medicare Appeals Council is substantively invalid because it is contrary to statute or regulation. Although other litigants have prevailed on substantive challenges to similar decisions, Mrs. Smith has clearly waived any substantive challenge here.

As for the challenges that she has brought, Mrs. Smith's argument for issue preclusion fails for three separate reasons. *First*, issue preclusion can be waived even where it would otherwise apply, and Mrs. Smith waived any argument for preclusion when she did not present it to the Medicare Appeals Council in the proceedings below. *Second*, Medicare coverage decisions by administrative law judges do not give rise to preclusive effect, as two district courts have recently

held. *Third*, issue preclusion can only apply where "the party against whom the doctrine is invoked was a party or in privity with a party to the prior adjudication," *Murdock v. Ute Indian Tribe of Uintah & Ouray Reservation*, 975 F.2d 683, 687 (10th Cir. 1992), and the Secretary was not a party to the earlier proceedings before an administrative law judge.

Finally, Mrs. Smith cannot obtain vacatur of a CMS Ruling in a case for "judicial review of the Secretary's final decision" on individual Medicare coverage claims. 42 U.S.C. § 1395ff(b)(1)(A). In such a case, the court only has "power to enter . . . a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing." *Id.* § 405(g). Because issue preclusion does not apply here, and vacatur of a CMS Ruling is not authorized, Mrs. Smith's motions for summary judgment should be denied, and summary judgment should be entered in favor of the Secretary.

BACKGROUND

A. Medicare Part B and CMS Ruling 1682-R

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, which is administered on behalf of the Secretary of Health and Human Services by the Centers for Medicare & Medicaid Services (CMS). Part A of the Medicare statute "covers medical services furnished by hospitals and other institutional care providers." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5). Medicare Part B "is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including outpatient physician services" and "durable medical equipment" (DME), among other things. *Id.* (citing 42 U.S.C. §§ 1395j to 1395w-4). *See* 42 U.S.C. § 1395x(n); 42 C.F.R. § 414.202 (defining "durable medical equipment").

In 2017, the Secretary issued a CMS Ruling—a "statement of policy or interpretation" that is "binding on all CMS components," 42 C.F.R. § 401.108; *see id.* § 405.1063(b)—on the subject of Part B coverage for continuous glucose monitors. CMS Ruling 1682-R (Jan 12, 2017), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf. The CMS Ruling said continuous glucose monitors that could be used to guide treatment decisions "such as changing one's diet or insulin dosage based solely on the readings of the CGM," *id.* at 7, would be covered as durable medical equipment under the terms of the CMS Ruling, *id.* at 8, but that other CGMs would not, *id.* at 15. The Secretary has since published a notice of proposed rulemaking which would, if finalized, "classify CGM systems . . . as DME" whether or not they can be used to make treatment decisions on the basis of their readings alone. 85 Fed. Reg. 70,358, 70,403–04 (Nov. 4, 2020). The public comment period closed on January 4, 2021.

B. Medicare Coverage Determination and Claim Appeal Process

To seek reimbursement for the cost of a continuous glucose monitor or anything else, "a Medicare Part B beneficiary must submit a claim for an 'initial determination' of whether 'the items and services are covered or otherwise reimbursable.'" *Porzecanski v. Azar*, 943 F.3d 472, 475–76 (D.C. Cir. 2019) (quoting 42 C.F.R. § 405.920); *see* 42 U.S.C. § 1395ff(a)(1). "Initial coverage determinations are made by" Medicare administrative contractors hired by the agency "to manage the preliminary claims administration process." *Porzecanski*, 943 F.3d at 476. "If the contractor denies the beneficiary's claim," he may "obtain a 'redetermination' from the same contractor." *Id.* (citing 42 U.S.C. § 1395ff(a)(3)(A); 42 C.F.R. § 405.940). "If unsuccessful, the beneficiary can seek 'reconsideration' by a 'qualified independent contractor' who is wholly independent of the initial determination contractor." *Id.* (citing 42 U.S.C. § 1395ff(c)(1)–(2); 42

C.F.R. § 405.960). The agency is not a party to the proceedings on initial determination, redetermination, or reconsideration. 42 C.F.R. § 405.906(a)–(b).

If the beneficiary remains unsatisfied, subject to a minimum amount-in-controversy requirement, "he can request a hearing before an administrative law judge (ALJ)." *Porzecanski*, 943 F.3d at 476 (citing 42 C.F.R. § 405.1000); *see* 42 U.S.C. § 1395ff(b)(1)(E) & (d)(1). In the proceedings before the ALJ, the agency may choose to participate as a party if (and only if) the beneficiary is represented. *See* 42 C.F.R. § 405.1012(a)(1). The agency must choose to participate "no later than 10 calendar days after receipt of the notice of hearing by the [qualified independent contractor] or another contractor designated by CMS to receive the notice of hearing," or else forfeit the right. *Id.*

After the ALJ issues a decision, the beneficiary can seek review by the Medicare Appeals Council, *see* 42 C.F.R. § 405.1100, which makes the final decision for the Secretary, *id.* § 405.1130. If the agency has participated as a party before the ALJ, then it may seek Appeals Council review on approximately the same terms as any other party. *Id.* §§ 405.1102(a)(1), 405.1108(a), 405.1110(b)(1)(i) & (c)(1). If, however, the agency has not participated as a party before the ALJ, then it may only request Appeals Council review in cases where it believes that the decision "contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest." *Id.* § 405.1110(b)(1). The Appeals Council may deny review if it disagrees. *Id.* § 405.1110(c)(2). Review before the Medicare Appeals Council (which is housed within the Departmental Appeal Board, or "DAB") is "de novo." 42 U.S.C. § 1395ff(d)(2)(B); *see* 42 C.F.R. § 405.1100(c) ("When the Council reviews an ALJ's . . . decision, it undertakes a de novo review.").

If the beneficiary is not satisfied with the decision of the Council then, subject to another amount-in-controversy requirement, 42 U.S.C. § 1395ff(b)(1)(E), he is entitled "to judicial review of the Secretary's final decision . . . as is provided in section 405(g) of this title," *id.* § 1395ff(b)(1)(A), which in turn provides that "[t]he court shall have power to enter . . . a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing," *id.* § 405(g). The agency may not seek judicial review.

C. Procedural Background

In 2018, Mrs. Smith received a favorable decision from an administrative law judge regarding the coverage of a continuous glucose monitor. A copy of this ALJ decision appears in the record at AR 1405–12. Although the full record of that proceeding is not before this Court, the decision in ALJ Appeal No. 1-6020086584R1 indicates that a favorable decision was first issued in 2017, after which CMS requested review by the Medicare Appeals Council, *see* 42 C.F.R. § 405.1110(b)(1), which vacated the initial decision and remanded to the ALJ for further proceedings. AR 1405. On remand, the ALJ held a hearing at which Mrs. Smith was represented by counsel. *Id.* The record does not indicate that the agency participated as a party in ALJ Appeal No. 1-6020086584R1 or the earlier proceedings. *See id.*

The appeal concerned a claim for Medicare Part B coverage of "continuous glucose monitor sensors" furnished to Mrs. Smith "for use with [her] continuous glucose monitor" on October 29, 2015. AR 1406. The ALJ decision does not precisely describe the device in question, but simply refers to it as a "continuous glucose monitor." *E.g.*, AR 1410 ("The sensors at issue are used with a continuous glucose monitor."). The ALJ concluded that Mrs. Smith's "continuous glucose monitor meets the definition of durable medical equipment set forth in 42 C.F.R. § 414.202," and that "the continuous glucose monitor sensors . . . at issue were reasonable and

necessary and met Medicare criteria for reimbursement" as supplies for a piece of durable medical equipment. AR 1411. The decision in ALJ Appeal No. 1-6020086584R1 issued on April 24, 2018. AR 1412.

The decision under review here concerns three claims, which were reviewed in two separate ALJ proceedings, and then subject to a single decision by the Medicare Appeals Council. The first claim was for a MiniMed 630G system with Smartguard—an insulin pump that also functions as a continuous glucose monitor—received by Mrs. Smith on December 13, 2016. The second claim was for disposable sensors received on November 16, 2017, and the third was for sensors received on May 15, 2018. All three claims were initially denied, and the denials were affirmed on redetermination and reconsideration. *See* AR 5. Mrs. Smith then sought ALJ review. In Appeal No. 1-8048536100, the ALJ concluded that because the device at issue "is not an FDA approved device for making diabetes treatment decisions without the use of a blood glucose monitor," AR 30, it is not durable medical equipment under the Medicare statute and regulations as interpreted by CMS Ruling 1682-R, AR 31–32. He therefore affirmed the denial of coverage for the first two claims. AR 32. The denial of the third claim was affirmed by the same ALJ in Appeal No. 1-8048583213, for the same reasons, in a decision issued the same day. AR 38–47. The Medicare Appeals Council affirmed the denial of all three claims, explaining that because "the FDA has not approved the beneficiary's CGM system, a Medtronic Minimed 630G with Smartguard[,] as a replacement for a blood glucose monitor," "the CGM at issue is not DME under the CMS ruling," and where, "as is the case here, . . . the items at issue are supplies to be used with equipment that is not classified as DME, there is no Medicare benefit." AR 10–11. Mrs. Smith then sought judicial review.

STATEMENT OF UNDISPUTED MATERIAL FACTS AND RESPONSE TO PLAINTIFF'S STATEMENTS

"[W]hen a party seeks review of agency action . . . , the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "The entire case on review is a question of law," and the "complaint, properly read . . . presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); *accord Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009); *Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 440 n.3 (D.C. Cir. 1999); *James Madison Ltd. v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). At summary judgment, the district court's review "is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously," *Rempfer*, 583 F.3d at 865, or in violation of another legal standard.

For that reason, the Local Civil Rules of this Court provide a special mechanism for cases involving judicial review of agency action, which omits the usual statement of undisputed facts. *See* Local Civil Rule 7-4. In this case, however, the parties are filing summary judgment motions under Federal Rule of Civil Procedure 56 and Local Civil Rule 56-1. The Secretary therefore provides the following brief statement of undisputed material facts in accordance with Local Civil Rule 56-1(b)(3) and (c)(4), and responds to plaintiff's statements in accordance with Local Civil Rule 56-1(c)(3), which provides that "[t]he non-moving party should not restate all the moving party's statement of facts and should only respond to those facts for which there is a genuine dispute of material fact."

A. Defendant's Statement of Undisputed Material Facts

1. Mrs. Smith did not argue to the Medicare Appeals Council that the decision in ALJ Appeal No. 1-6020086584R1 should have issue preclusive effect in the Appeals Council decision under review here. AR 12–15.

2. Neither the Secretary nor CMS participated as a party in ALJ Appeal No. 1-6020086584R1. AR 1405–12.

B. Response to Plaintiff's Statements of Facts

i. Collateral Estoppel, ECF No. 29

"The Secretary had a full and fair opportunity to litigate before ALJ Lambert. See AR1405; Exhibit B at ¶ 65; Exhibit C at ¶ 65."

Response: This statement is a legal conclusion, not a factual claim. The Secretary's response appears at page 16 in the argument section below.

"ALJ Lambert determined that Mrs. Smith's CGM (and supplies) were 'durable medical equipment', 'primarily and customarily used to serve a medical purpose', 'medically reasonable and necessary', and a covered Medicare benefit. *See* AR1410; AR1411; AR1406."

"ALJ Lambert's determination that Mrs. Smith's CGM (and supplies) were 'durable medical equipment', 'primarily and customarily used to serve a medical purpose', 'medically reasonable and necessary' were a necessary component to finding Medicare coverage. *See* AR1405-1412."

"ALJ Lambert's decision became final on or after June 25, 2018. See Exhibit B at ¶74; Exhibit C at ¶74."

Response: These are not factual claims, but rather legal conclusions and characterizations of a record document: the decision in ALJ Appeal No. 1-6020086584R1, which does not precisely

describe the device in question, but simply refers to it as a "continuous glucose monitor." *See* AR 1405–12.

"ALJ Win found that Mrs. Smith's CGM was not 'durable medical equipment.' *See* AR30-32."

"ALJ Win found that Mrs. Smith's CGM was not 'durable medical equipment' and not a Medicare covered benefit. *See* AR30-32."

Response: These are not factual claims, but rather legal conclusions and characterizations of a record document: the decision in ALJ Appeal No. 1-8048536100. *See* AR 23–32. To the extent these statements suggest that the devices at issue in ALJ Appeal Nos. 1-6020086584R1 and 1-8048536100 were one and the same (both are described as "Mrs. Smith's CGM"), that is not demonstrated by the administrative record. The device at issue in ALJ Appeal No. 1-8048536100 —one of the two ALJ decisions reviewed by the Medicare Appeals Council in M-19-1973, the decision under review here—was "a MiniMed 630G with Smartguard," AR 3, which is an insulin pump. The decision in ALJ Appeal No. 1-6020086584R1 does not precisely describe the device in question, but simply refers to it as a "continuous glucose monitor." *See* AR 1405–12.

ii. Challenge to CMS Ruling 1682-R, ECF No. 28

"Prior to January 12, 2017, numerous ALJs had determined that a CGM which does not replace a home glucose monitor was 'primarily and customarily used to serve a medical purpose' and was covered 'durable medical equipment.' *See* Exhibit A at ¶9; AR 38-47."

Response: To the extent that this is a factual statement, rather than a characterization of ALJ decisions contained in the administrative record, it is not material to plaintiff's claim that CMS Ruling 1682-R is procedurally invalid.

"Prior to January 12, 2017, there was no policy, binding on ALJs and the MAC, precluding ALJs and the MAC from finding that a CGM which does not replace a home glucose monitor is covered 'durable medical equipment.' *See* Exhibit A at ¶9; AR 38-47."

"Prior to January 12, 2017, there was no policy, binding on ALJs and the MAC, precluding ALJs and the MAC from finding that a CGM which does not replace a home glucose monitor is 'primarily and customarily used to serve a medical purpose.' *See* Exhibit A at ¶9; AR 38-47."

"Prior to January 12, 2017, ALJs and the MAC had discretion to determine that CGMs which do not replace a home glucose monitor are covered 'durable medical equipment. *See* Exhibit A at ¶9; AR 38-47."

Response: These are not factual statements, but rather legal conclusions and characterizations of record documents—and in any event are not material to plaintiff's claim that CMS Ruling 1682-R is procedurally invalid. It is not disputed that, prior to January 12, 2017, there was no CMS Ruling or national coverage determination applying the statutory and regulatory definition of durable medical equipment to continuous glucose monitors.

"CMS 1682-R established the new categories of 'therapeutic' and 'non-therapeutic' CGMs with regard to coverage. See Exhibit B at 6-9."

Response: This is not a factual statement, but rather a characterizations of a record document—and in any event is not material to plaintiff's claim that CMS Ruling 1682-R is procedurally invalid. CMS Ruling 1682-R used the term "therapeutic" to refer to the class of continuous glucose monitors that it found to be primarily and customarily used to serve a medical purpose, and used the term "non-therapeutic" to refer to such devices that it determined were not so used. These were not "new categories" "established" by the CMS Ruling, but rather terms of

art used to apply pre-existing categories established by regulation to the case of continuous glucose monitors. *See* 42 C.F.R. § 414.202.

"Without notice and comment, CMS 1682-R was incorporated into LCD L33822 and Policy Article A52464. See Exhibit C, Exhibit D, Exhibit F at ¶37, Exhibit G at ¶37."

Response: It is unclear what plaintiff means by "incorporated into." It is undisputed that this local coverage determination and policy article referred to CMS Ruling 1682-R, and were not preceded by notice and an opportunity to comment.

ARGUMENT

A. Collateral estoppel did not preclude the challenged decision.

i. By failing to raise the issue before the Medicare Appeals Council, plaintiff waived any claim that an earlier ALJ decision should be accorded preclusive effect.

Mrs. Smith's first motion argues that the Medicare Appeals Council was precluded from reaching the decision challenged here, on account of the earlier decision in ALJ Appeal No. 1-6020086584R1. But Mrs. Smith waived any such argument by failing to present it in the administrative process.

Mrs. Smith's letter brief to the Medicare Appeals Council, dated June 4, 2019, appears at AR 12–15. Although it argues for issue preclusion on the question of coverage, it does so on the basis of *district court opinions to which Mrs. Smith was not a party*. AR 13–14. The brief never so much as mentions the decision in ALJ Appeal No. 1-6020086584R1, and certainly does not argue that the outcome there should have controlled the coverage determination here. Mrs. Smith has therefore waived any argument that it does, because an argument for preclusion "must be timely raised." *Seneca-Cayuga Tribe of Okla. v. Nat'l Indian Gaming Comm'n*, 327 F.3d 1019, 1029 (10th Cir. 2003). The Tenth Circuit has "applied this rule to bar a party from raising an

estoppel argument on appeal where that party . . . failed to timely raise its estoppel claim below." *Id.* (citing *Harvey v. United Transp. Union*, 878 F.2d 1235, 1243 (10th Cir. 1989)). And the regulations governing Medicare Appeals Council review clearly require issue exhaustion. *See* 42 C.F.R. § 405.1112(b) ("The request for review must identify the parts of the ALJ's . . . action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's . . . decision, dismissal, or other determination being appealed."); *id.* § 405.1112(c) ("The [Medicare Appeals] Council will limit its review of an ALJ's . . . actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary."). An argument for issue preclusion must therefore be presented to the Medicare Appeals Council if it is to be preserved for judicial review. *See Zieroth v. Azar*, 2020 WL 5642614 (N.D. Cal. Sept. 22, 2020) (arguments not presented to the Medicare Appeals Council are waived).

Because Mrs. Smith did not argue to the Medicare Appeals Council that the decision in ALJ Appeal No. 1-6020086584R1 should give rise to issue preclusion, she cannot press that argument before this Court. For that reason alone, the Secretary is entitled to summary judgment on the question of issue preclusion.

ii. ALJ decisions on Medicare coverage claims do not give rise to issue preclusion.

And even if Mrs. Smith's argument for collateral estoppel had been preserved, it would be unavailing, because ALJ decisions regarding Medicare coverage claims lack preclusive effect. *See, e.g.*, 81 Fed. Reg. at 43,793 ("Individual determinations and decisions by . . . OMHA ALJs . . . are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals."). Two district courts have recently upheld this principle against the very arguments presented by plaintiff's counsel here. *See Banks v. Azar*, 2021 WL 1759304, at *4 (N.D. Ala. Mar. 30, 2021) ("Based on the statutory and regulatory scheme of the

Medicare Act, it is clear that application of collateral estoppel in Medicare matters runs counter to legislative intent and ALJ decisions should not be given preclusive effect."); *Christenson v. Azar*, 2020 WL 3642315, at *7 (E.D. Wis. July 6, 2020) ("Plaintiffs have failed to demonstrate that it is appropriate to apply the doctrine of collateral estoppel on the basis of ALJ-level decisions in the Medicare context."). Although there are significant doubts as to the standing of the plaintiffs in *Banks* and *Christenson*, the analysis of those district courts was sound.[1]

Both district courts concluded that the Secretary's regulations governing the Medicare Appeals Council were a valid implementation of the governing statute. Those regulations empower the chair of the Departmental Appeal Board to "designate a final decision of the Secretary issued by the Medicare Appeals Council . . . as precedential." 42 C.F.R. § 401.109(a). "Medicare Appeals Council decisions [so] designated . . . are binding on all CMS components, [and] on all HHS components that adjudicate matters under the jurisdiction of CMS," including ALJs. *Id.* § 401.109(c). Under this regulation, "precedential effect" means that the Appeals Council's legal interpretations are binding on all parties, *id.* § 401.109(d)(1), and that its "[f]actual findings are binding and must be applied to future determinations and appeals involving the same parties," *id.* § 401.109(d)(2). The clear implication of these regulations is that decisions of the Medicare Appeals Council have no precedential effect *even between the same parties* unless a

[1] The opinion in *Banks* was vacated by the Eleventh Circuit and remanded to the district court for an assessment of plaintiff's standing. *Banks v. Sec'y of HHS*, 2021 WL 3138562 (11th Cir. July 26, 2021).

After issuing its opinion on collateral estoppel, the *Christenson* court concluded that the only remaining plaintiff lacked standing. The case was heard on appeal as *Prosser v. Becerra*, and the Seventh Circuit affirmed the dismissal for lack of standing. 2 F.4th 708 (7th Cir. 2021); *see also id.* at 712 ("In July 2020 the district court entered partial summary judgment for the Secretary, concluding that administrative Medicare coverage decisions made by ALJs did not bind future coverage decisions. Put another way, the doctrine of collateral estoppel does not apply to these administrative coverage decisions.").

particular decision is expressly designated as precedential. And the regulations do not provide any circumstance under which a prior *ALJ* decision could have preclusive effect. *Banks*, 2021 WL 1759304 at *4 ("Since, the regulations are explicit about the precedential effect that a decision by the Council would carry, the implication arises that other appellate levels are distinguished from these precedential decisions. This would mean that an ALJ decision would not have a binding effect . . . ."); *Christenson*, 2020 WL 3642315 at *5 ("It follows that, as the Secretary argues, ALJ decisions are not binding on another ALJ [or the Appeals Council] as only Council-level decisions can carry binding effect."); *see Porzecanski*, 943 F.3d at 485 (explaining that "ALJ decisions are non-precedential" for Medicare coverage claims). "This understanding is embodied by the Secretary's definition of 'precedential effect' and represents a policy decision that Congress has delegated to the Secretary to implement in administering Medicare's internal review process." *Christenson*, 2020 WL 3642315 at *7.

The *Banks* court also found it significant that the statute instructs the Medicare Appeals Council, when "reviewing a decision on a hearing" held by an ALJ, to "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B); *see* 42 C.F.R. § 405.1100(c). "To bind the Council to a decision of an [earlier] ALJ, the Council could not perform a de novo review that the statute and regulations require." *Banks*, 2021 WL 1759304 at *4. And the *Banks* court noted that "several sister circuits share the view that ALJ decisions are not binding upon other ALJs or the Board [*i.e.*, the Appeals Council]." *Id.* (citing *W. Texas LTC Partners, Inc. v. Dep't of Health & Human Servs.*, 843 F.3d 1043, 1046 (5th Cir. 2016) ("[P]rior ALJ decisions are not binding on the DAB or other ALJs."); *Porzecanski*, 943 F.3d at 477 ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.")); *accord Christenson*, 2020 WL 3642315 at *5.

As the Secretary's valid regulations make clear, as two district courts have recently held, and as courts of appeals have acknowledged, ALJ decisions regarding Medicare coverage claims never give rise to the issue preclusive effect that Mrs. Smith claims here. The Secretary is therefore entitled to summary judgment on the question of issue preclusion.

iii. The decision in ALJ Appeal No. 1-6020086584R1 does not satisfy the Tenth Circuit's test for issue preclusion, principally because the Secretary was not a party to that administrative proceeding.

And even if ALJ decisions could sometimes give rise to issue preclusion, the decision in ALJ Appeal No. 1-6020086584R1 would not do so. "For an issue to be collaterally estopped, the party invoking the doctrine has the burden of establishing" that, as relevant here, "the party against whom the doctrine is invoked was *a party or in privity with a party* to the prior adjudication, and . . . had a *full and fair opportunity to litigate* the issue in the prior action." *Stan Lee Media, Inc. v. Walt Disney Co.*, 774 F.3d 1292, 1297 (10th Cir. 2014) (quoting *Murdock v. Ute Indian Tribe of Uintah & Ouray Reservation*, 975 F.2d 683, 687 (10th Cir. 1992)) (emphasis added in *Stan Lee*). Mrs. Smith cannot make either showing.

To begin with, the Secretary was not "a party or in privity with a party" to the decision in ALJ Appeal No. 1-6020086584R1. The only party was Mrs. Smith. Although CMS could have participated as a party, *see* 42 C.F.R. § 405.1012(a)(1), the agency did not do so. Mrs. Smith seems to suggest that because she bore the burden of proof at the ALJ hearing, the Secretary was effectively a party. ECF No. 29 at 18–19. But she offers no authority for that proposition, which would defeat the purpose of this requirement: to ensure that the collaterally estopped issue was actually subject to the adversarial process. *See* Restatement (Second) of Judgments § 27, cmt. a ("The rule of issue preclusion is operative where the second action is between the same persons who were parties to the prior action, *and who were adversaries . . . with respect to the particular*

issue . . . ." (emphasis added)). Because Mrs. Smith was the only party to ALJ Appeal No. 1-6020086584R1, she cannot use that decision as the basis for issue preclusion here.

Nor did the Secertary have a "full and fair opportunity to litigate" the ostensibly precluded issue in ALJ Appeal No. 1-6020086584R1. Mrs. Smith suggests that, because CMS could have participated as a party (but did not) the Secretary therefore had such an opportunity. *See* ECF No. 29 at 19–20. She is incorrect. "The requirement that the party against whom the prior judgment is asserted had a full and fair opportunity to be heard centers on the fundamental fairness of preventing the party from relitigating *an issue he has lost in a prior proceeding*." *SIL-FLO, Inc. v. SFHC, Inc.*, 917 F.2d 1507, 1521 (10th Cir. 1990) (emphasis added). In this way, the requirement presumes that the party against whom collateral estoppel is asserted has previously litigated and lost. That is not true of the Secretary here. "Often, the inquiry will focus on . . . whether the party had the incentive to litigate fully the issue . . . ." *Id.* Again, the Secretary did not: any incentive to litigate the issue was substantially diminished by the understanding that the ALJ's determination would affect nothing more than the coverage claim before him, as discussed above.

Mrs. Smith suggests a rule in which the preclusive effect of ALJ decisions to which the agency was not a party would turn on the question of *whether the Medicare beneficiary was represented*. Decisions in favor of represented parties would give rise to preclusive effect, while decisions in favor of unrepresented parties would not. But the question for issue preclusion is whether the Secretary was actually a party to the prior proceeding—not whether he could have been, as Mrs. Smith would have it. Even if Mrs. Smith had preserved her argument for collateral estoppel (which she did not), and ALJ decisions could sometimes bind the Medicare Appeals Council (which they cannot), a non-adversarial ALJ proceeding in which the Secretary did not

participate still would not give rise to the issue preclusion asserted here. The Secretary is entitled to summary judgment on the question of issue preclusion.

B. This Court cannot and should not vacate CMS Ruling 1682-R.

Mrs. Smith's second motion argues that this Court can and should vacate CMS Ruling 1682-R as procedurally flawed, and order coverage of the claims at issue here. *See* ECF No. 28. But this Court lacks authority to do so. Even if this Court were to conclude that CMS Ruling 1682-R was invalid for lack of notice and an opportunity for public comment, it could not exceed the scope of the jurisdiction conferred by Congress in the Medicare statute, which only authorizes "judicial review of the Secretary's final decision . . . as is provided in section 405(g) of this title." 42 U.S.C. § 1395ff(b)(1)(A); *see Porzecanski*, 943 F.3d at 480 ("Federal jurisdiction is extremely limited for claims arising under the Medicare Act."). That provision, in turn, gives "[t]he court . . . power to enter . . . a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing." *Id.* § 405(g). It does not authorize vacatur of other agency actions, such as CMS Rulings, in a case for "judicial review of the Secretary's final decision." *Id.* § 1395ff(b)(1)(A).

If the Secretary's final decision—which is the action under review here—improperly relied on a procedurally invalid CMS Ruling, then the remedy is a remand so that the Secretary can decide Mrs. Smith's claim without reference to the disputed Ruling. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 201 (1947) ("After the remand was made, therefore, the Commission was bound to deal with the problem afresh, performing the function delegated to it by Congress.")). Any procedural failing in the decision of the Appeals Council should not—and logically, could not—lead this Court to impose the opposite substantive result.

CONCLUSION

Issue preclusion does not apply here, and vacatur of CMS Ruling 1682-R is not authorized. Mrs. Smith's motions for summary judgment should therefore be denied, and summary judgment should be entered in favor of the Secretary.

Dated: September 21, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

MICHELLE BENNETT
Assistant Director, Federal Programs Branch

/s/ James Bickford
JAMES BICKFORD
Trial Attorney (N.Y. Bar No. 5163498)
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20530
James.Bickford@usdoj.gov
Telephone: (202) 305-7632
Facsimile: (202) 616-8470

Counsel for Defendant